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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,999	11/24/2003	Valentino Montegrando	0424-06	3376

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT PAPER NUMBER

3737

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/720,999

Applicant(s)

MONTEGRANDE, VALENTINO

Examiner

Jaworski Francis J.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

I. Transport Catheter-Delivered Imaging Probe

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Taimisto et al (US5351693).

Taimisto et al is directed to a catheter-within-a-catheter system where catheter 10 is a larger transport catheter with an enlarged internal work lumen 36 (Fig.1 and the Fig. 2 cross-section), into which lumen the ultrasound probe 82

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shown in Fig. 7 is inserted and thereby delivered to the internal worksite without traumatizing tissue after the transport catheter has been introduced. Therefore:

Taimisto et al teaches an ultrasound imaging system (Note that while the transducer 92 is omni-directional and therefore directionally non-specific insofar as it is cylindrical, an M-mode or echo-line versus time image is none-the-less produced, see col. 12 lines 61 – 69) comprising

an ultrasound probe 82 adapted to be placed in an instrument working channel 36,

the probe having a probe housing 84 and 140, 142, an ultrasound transducer 92 mounted therein, an elongate flexible cord 96 and/or 98 and its portions described col. 8 line 65 – col. 9 line 35 which extend from the probe housing through the working channel 36 when probe 82 is placed therein, and are adapted to couple to a personal computer, see col. 11 lines 17 – 28.

Hence the argument is made that Taimisto et al anticipates the claimed structure since it is an ultrasound image-producing probe adapted to be passed within a working channel of an internal probe and be connected with a computer, and such a placement adaptation would enable endoscopic placement via a similarly sized working channel.

II. Endoscopically Delivered Ultrasound Imaging Probe

Claim 1 is further rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al (US4802487) or in the alternative under 35 USC 103 as obvious over Martin et al. alone or further in view of Ishimura et al (US5255681)..

[Martin et al is one of three patents directed to endoscopically deliverable ultrasound mini-probes involving inventor Silverstein and a Seattle-based research group, the others being US4582067 directed to Doppler not imaging and US5178150 directed to imaging but with emphasis on mechanical probe design as opposed to signal processing and which latter patents are not applied but are merely cited to complete the record].

Martin et al teaches an ultrasound imaging system comprising:

An ultrasound probe 6,8, 190 adapted to be placed in the instrument working channel 5 of an endoscope 2, the probe having a probe housing 194 (Fig. 9 embodiment) within which transducer 190 is mounted, and an elongate flexible cord 202, 204 extending from the housing and through the working channel 5. Since Martin et al feeds an extensive signal processing system of Figs. 18 and 19 by conductor leads 202, 204 inputting to 302,306 of Fig. 18, which leads become multiplied when an array is used, see 235-238 of Fig. 15A, while displacement sensor leads 132, 134, 136 of Fig. 7 feeding to 362 of Fig. 18 are also present, it is argued that such a lead complexity as well as Fig. 18-19 complexity adapts itself to computer control and this adaptability is all that is claim 1 requires since the computer per se is not claimed.

In the alternative, if Martin et al be argued to fall short of being inherently adapted for use with a computer, it would have been obvious in view of Ishimura

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et al Figs. 7-9 specifically elements 34 and 41A and col. 11 lines 22 – 29 to use a personal computer to control the synchronizing and data complexity of an ultrasound endoscopic imager using a personal computer because it is cumbersome to design such a system in hardware only.

Hence the Examiner is arguing that the Martin et al endoscopically deliverable ultrasound imaging probe meets all of the claimed structure, or in the alternative the artisan would know to utilize Martin et al with a PC-controlled system since such were used with endoscopic ultrasound imaging probes and therefore would logically extend to use with endoscopically deliverable imaging mini-probes.

III. Obvious Extension of Personal Computer-based UTS Imaging

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chiang et al .(US5957846) in view of Martin et al (US4802487).

Chiang et al is directed to portabilizing an ultrasound imaging system by use with a laptop personal computer as opposed to a larger wheeled cart-based system. As such it is directed to miniaturizing and diminishing power requirements and reducing lead numbers from the probe proper. Figs. 40A and 40B and col. 34 lines 32 – 55 represent a device variant of an ultrasound imaging probe or catheter insertable into a body lumen (the term 'endoscope' is not specifically used.). Hence:

Chiang et al teach an ultrasound imaging system comprising

An ultrasound probe 902, 907 which is endoscope-like and including a probe housing 922, an ultrasound transducer array 918 mounted within the housing, an elongate cord (cable) 920 which is flexible since the surrounding insertion shaft 902 is flexible, the cord being adapted to extend internal to the housing and therefore internal to whatever the housing is placed into, and to operably connect the ultrasound transducer with a computer housed within 904 (since a personal computer with graphical user interface is envisioned for all embodiments, see claim 6 for example).

Chiang et al does not teach an endoscopically deliverable ultrasound imaging probe but rather an endoscope-like ultrasound imaging probe. However it would have been obvious in view of Martin et al to deliver an endoscope-like probe within an endoscope since this allows delivery to the worksite with the advantages such as optical forward viewing of the larger endoscope system.

Hence the Examiner is arguing that the endoscopically deliverable computer-run ultrasound imaging probe is an obvious variant of the endoscope-like computer-run ultrasound imaging probe.

IV Co-Registered Esophageal Endoscope

Claim 1 is further rejected under 35 U.S.C. 102(b) as being anticipated by Miller (US5878749).. Miller is directed to combined pressure manometry and ultrasound imaging in order to assess an esophageal varix and therefore teaches

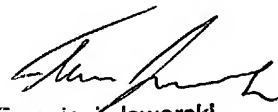
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An ultrasound imaging system comprising:

An ultrasound imaging probe 101 (col. 4 lines 32 – 36) which in the Fig. 3 - 4 embodiment is adapted to be placed within the working channel of a fiberoptic/video endoscope (col. 5 lines 50-52), the probe having a probe housing 305 (since it is placed into this balloon endoscope device which serves as its housing) and a flexible cord adapted to fit through the working channel of the placement endoscope and for connecting it the ultrasound imaging device 115, which device may include a computer (Col. 4 lines 39-46).

Hence the argument is made that such a nested or co-registered multifunctional imaging and sensor device when endoscopically delivered into the proximal region of the GI tract is readable against the base claim.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 703-308-3061.


Francis J. Jaworski
Examiner

FJJ:fjj

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